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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-------------------------|------------------------|------------------|
| 10/070,882 | 03/11/2002 | Richard William Titball | 41577/270459 | 2737 |
| 7590 | 09/29/2004 | | EXAMINER | |
| John S Pratt Kilpatrick Stockton Suite 2800 1100 Peachtree Street Atlanta, GA 30309-4530 | | | DEVI, SARVAMANGALA J N | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/070,882 | TITBALL ET AL. |
| | Examiner | Art Unit |
| | S. Devi, Ph.D. | 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10/14/03.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 7-15 and 17-22 are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-4, 7-15 and 17-22 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Lack of Unity of Invention(s)

- 1) Claims 2-4 and 7-15 have been amended.
Claims 5, 6 and 16 have been canceled.
New claims 17-22 have been added.
Claims 1-4, 7-15 and 17-22 are under prosecution.
- 2) The instant inventions lack unity under PCT Rule 13.1 and 13.2:
 - I. Claims 1-4, 7-15 and 17-22, drawn to a method of enhancing expression of a desired protein at mucosal effector sites by placing the protein to be expressed under the control of *phoP* promoter (SEQ ID NO: 2) and a recombinant gut-colonizing microorganism transformed with a construct comprising a P*phoP* promoter.
 - II. Claims 1-4, 7-15 and 17-22, drawn to a method of enhancing expression of a desired protein at mucosal effector sites by placing the protein to be expressed under the control of *pagC* promoter (SEQ ID NO: 3) and a recombinant gut-colonizing microorganism transformed with a construct comprising a P*pagC* promoter.
 - III. Claims 1-4, 7-15 and 17-22, drawn to a method of enhancing expression of a desired protein at mucosal effector sites by placing the protein to be expressed under the control of *ompC* promoter (SEQ ID NO: 4) and a recombinant gut-colonizing microorganism transformed with a construct comprising a P*ompC* promoter.
 - IV. Claim 20, drawn to a recombinant microorganism transformed with a construct comprising a promoter having the sequence of SEQ ID NO: 1.
- 3) Inventions I-IV are drawn to multiple inventions that lack unity of inventions. The special technical features of inventions I-III are delineated above, which do share significant method steps, reagents or products used in the methods. The product of invention IV has a promoter which does not share significant structural features with the promoters used in the products and methods of inventions I to III. The promoters used in the product of inventions I, II and III do not share significant structure or amino acid composition with each other or with the promoter contained in the product of invention IV.
- 4) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions

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24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

5) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER